Boston Scientific

K060947

APR 19 2006

510(k) Summary of Safety and Effectiveness

Boston Scientific Corporation

Sonicath Ultra™ 3.2F 20MHz Imaging Catheter

Submitted By:

Boston Scientific Corporation
IVUS Technology Center
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Contact Person:

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Date Prepared: April 5, 2006

Proprietary Name: Sonicath Ultra™ 3.2F 20MHz Imaging Catheter

Common Name(s):
Ultrasound Diagnostic Imaging Catheter
Diagnostic Intravascular Catheter (74DQO)
Diagnostic Ultrasonic Transducer (90ITX)

Classification Name(s):
Diagnostic Intravascular Catheters, 21 CFR 870.1200 (74DQO)
Diagnostic Ultrasonic Transducers, 21 CFR 892.1570 (90ITX)

Predicate Device(s): Sonicath Ultra™ 3.2F 20MHz Imaging Catheter is substantially equivalent to the following device:

Predicate	510(k)	Clearance Date
Sonicath Ultra™ 3.2F 20MHz Imaging Catheter	K970049	June 20, 1997

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Description of the Device:

The Sonicath Ultra™ 3.2F 20MHz Imaging Catheter is a sterile, single-use, short rail (SR), 20 MHz imaging catheter with a 3.2F distal crossing profile. The catheter is intended to operate with the BSC ClearView Ultra™, Galaxy®, Galaxy²™, or iLab® intravascular ultrasound imaging instruments. The catheter and instrument form an imaging system that is intended for the ultrasonic examination of peripheral intravascular pathology only.

The catheter consists of two (2) main assemblies: a sheath assembly and an imaging core assembly. The sheath assembly is the outer part of the catheter that comprises much of the working length of the device. The imaging core is internal to the sheath assembly and rotates independently of the sheath. The imaging core contains the piezoelectric transducer that converts electrical energy from the instrument to ultrasonic energy that is in turn transmitted. The transducer converts the returned ultrasonic energy into electrical energy for display on the instrument. The rotating imaging core drive shaft directs the path of the ultrasonic energy (beam) from the transducer. A proximal telescoping section allows the imaging core to be retracted and advanced, across an anatomical region of interest, without requiring movement of the sheath within the anatomy.

Sonicath Ultra™ 3.2F 20MHz Imaging Catheter:

The modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter is identical in all aspects to the current Sonicath Ultra™ 3.2F 20MHz Imaging Catheter except for the following change:

- Changed catheter sheath support material from one Low Density Polyethylene (LDPE) resin formulation to another.

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Design verification testing confirms that predetermined acceptance criteria were met and no new issues of safety or efficacy have been raised with the use of this new catheter sheath support material.

Intended Use/Indications:

The Sonicath Ultra™ 3.2F 20MHz Imaging Catheter is intended for ultrasound examination of peripheral intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Device Technology Characteristics and Comparison to Predicate Device:

The modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter is the same as the predicate device, the Sonicath Ultra™ 3.2F 20MHz Imaging Catheter cleared June 20, 1997, in all aspects except one – change in sheath support resin formulation.

Non-clinical Test Results:

Bench and biological safety testing demonstrate that the modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter meets performance requirements and is safe and effective for its intended use.

Bench Testing:

Bench testing was performed to evaluate the physical integrity and functionality of the modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter. This testing included dimensional and functional (e.g., tensile, pressure) testing of the catheter sheath support and the full, sterile device. The results demonstrated that the device satisfies all performance, physical and functional requirements.

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Biological Safety Testing:

The Sonicath Ultra™ 3.2F 20MHz Imaging Catheter was subjected to a series of biocompatibility tests per USP and EN ISO 10993 standards. The results of the biocompatibility testing demonstrate that the modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter is acceptable for it intended use.

Acoustic Output Testing:

Acoustic Output testing was not required for the modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter as the formulation change to the sheath support has no effect on acoustic output.

Per the FDA Guidance, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 30 1997),* acoustic output measurements for the modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter remain unchanged from its predicate device, the Sonicath Ultra™ 3.2F 20MHz Imaging Catheter.

Conclusion:

The modified Sonicath Ultra™ 3.2F 20MHz Imaging Catheter utilizes the same design features and has the same intended use as the predicate device, the Sonicath Ultra™ 3.2F 20MHz Imaging Catheter. The tests conducted support a determination of substantial equivalence of the modified device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 1 2006

Mr. Robert Z. Phillips
Manager, Regulatory Affairs
Boston Scientific Corporation
IVUS Technology Center
47900 Bayside Parkway
FREMONT CA 94538-6515

Re: K060947
Trade Name: Sonicath Ultra™ Imaging Catheter
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: April 5, 2006
Received: April 6, 2006

Dear Mr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sonicath Ultra™ Imaging Catheter, as described in your premarket notification:

Transducer Model Number

3.2F 20MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

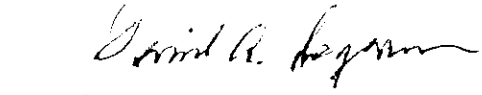
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ewa Czerska at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Indications for Use Statement

510(k) Number: K060947

Device Name: Sonicath Ultra™ 3.2F 20MHz Imaging Catheter

Indications for Use: The Sonicath Ultra™ 3.2F 20MHz Imaging Catheter is intended for ultrasound examination of peripheral intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Prescription Use___X___ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060947